HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

950360

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-05-01

October 8, 2004

MCR American Pharmaceuticals, Inc.
16206 Flight Path Drive
Brooksville, Florida 34604

Dear Sir / Madam:

This letter pertains to your marketing and distribution of the drug product "Allfen," an extended-release product containing a combination of 1,000 mg of guaifenesin and 150 mg of potassium guaiacolsulfonate.

On July 12, 2002, the Food and Drug Administration (FDA) approved an application for a single-ingredient guaifenesin 600-mg extended-release drug product. Following this approval, FDA reviewed the marketing status of all strengths of single-ingredient guaifenesin extended-release drug products and determined that those products should no longer be marketed in light of the existence of an approved product. On October 11, 2002, the agency sent warning letters to approximately sixty-six manufacturers and distributors regarding the marketing of unapproved single-ingredient guaifenesin extended-release products. The warning letters stated the agency's position that single-ingredient guaifenesin extended-release products are new drugs and require an approved new drug application for legal marketing under the Federal Food, Drug, and Cosmetic Act (the Act).

Through subsequent correspondence, the agency established the following timeframes for removal of the products from the market:

- The warning letter recipients were to stop manufacturing unapproved single-ingredient guaifenesin extended-release products no later than May 21, 2003, and were not to resume manufacturing until FDA approval of an application covering the particular products; and

- Distribution of unapproved single-ingredient guaifenesin extended-release products would continue until October 23, 2003. Distribution of single-ingredient guaifenesin extended release products could not resume after that date unless and until FDA approval of an application for the single-ingredient guaifenesin extended-release products.

FDA set those deadlines so that, with reasonable advance inventory planning by retailers, there would be no further sales of such products past November 2003.

Prior to November 2003, your product was sold as a single-ingredient guaifenesin extended-release product. Subsequently, your firm announced that it would launch a reformulated version of Allfen that added the potassium guaiacolsulfonate to the existing product.

The claims made for this product that include "nasal and chest congestion / thins out and promotes ejection of mucous / good for the elderly, hypertension (HTN) and COPD patients ... " cause it to fall within the definition of "drug" set forth at section 201(g) of the Act. Regarding your reformulated Allfen, FDA is unaware of substantial scientific evidence showing that a drug containing 1,000 mg guaifenesin and 150 mg potassium guaiacolsulfonate is generally recognized by qualified experts as safe and effective for its labeled indications. Accordingly, this product falls within the definition of "new drug" set forth at section 201(p) of the Act.

FDA has, through rule making procedures, accorded new drug status to certain drugs. 21 CFR § 310.502. Included among these are timed-release dosage forms. 21 CFR § 310.502(a)(14). Allfen's labeling describes it as a sustained-release formulation. FDA regards sustained-release formulations as timed-release dosage forms. Thus, Allfen is also a new drug within the meaning of section 201(p) of the Act pursuant to the rule governing this dosage form.

Finally, this product is also a new drug because it contains potassium guaiacolsulfonate. This ingredient was included in the review underlying FDA's development of over-the-counter (OTC) drug monographs. The panel reviewing potassium guaiacolsulfonate found it to be not effective. 41 Fed. Reg. 38367 (Sep. 9, 1976). FDA found the drug ineffective in its tentative final and final monographs for OTC expectorant drug products. Drugs containing this ingredient are currently considered new drugs and it is listed in 21 CFR § 310.545(a)(6)(iii) as a non-monograph OTC ingredient. See also 21 CFR § 300.50(a).

Section 505(a) of the Act requires that any new drug be the subject of an FDA-approved new drug application before its introduction into interstate commerce. There is no approved application on file for Allfen. The marketing of this product without an approved new drug application therefore violates Section 505(a) of the Act.

The violations described in this letter are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act.

We request that you take immediate action to correct the above-referenced violations. Please respond in writing to this office within fifteen working days of receipt of this letter, describing the specific actions that you will take, or have taken, to correct the violations. Your response should include an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be complete.

Failure to correct the referenced violations may result in regulatory action without further notice, including seizure and/or injunction. In addition, Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may take this information into account when considering the award of contracts.

We also note that your product uses the trade name associated with a previously marketed product by your firm that does not contain potassium guaiacolsulfonate. The association may confuse drug prescribers and dispensers, who are unaware that the Allfen product has been reformulated. Such confusion may result in your product being misprescribed, thereby risking dangerous drug interactions and overdoses. To address our concerns in this regard, please let us know of the steps that you have taken to advise both prescribers and dispensers of the changes to your products.

Your response to this letter should be directed to the attention of Jimmy E. Walthall, Director, Compliance Branch, Florida District, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone number (407) 475-4734.

Sincerely,

Emma R. Singleton
Director, Florida District
Food and Drug Administration

cc: Pharmakon Labs, Inc.
6050 Jet Port Industrial Blvd.
Tampa, Florida 33634